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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,461	12/04/2000	Marc Hendriks	P-8573	6569

27581 7590 06/25/2003

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	**PAPER NUMBER**
1632	9

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/727,461	Applicant(s) Hendriks
	Examiner Dave Nguyen	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 22, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above, claim(s) *7, 15-24, 31, 39-48, 53, and 54* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 8-14, 25-30, 32-38, and 49-52* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's election of Group I claims, claims 1-15, 25-38, and 49-52, the species of collagen, the species of polyglycolic acid in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed error in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is also noted that applicant are not intended to have the non-elected claims being canceled by examiner's amendment once prosecution is completed on the elected claims.

Claims 15-24, 39-48, 53, 54, 7, 31 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claimed invention or species (claims 7 and 31).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8, 9, 25-28, 32, 33, 35, 49, 51 are rejected under 35 USC 102(e) as being anticipated by, or in the alternative, under 35 USC 103(a), as being unpatentable over Brown, III *et al.* (US 6,219,577 B1, referred as Brown).

Brown teaches a medical device composed of a catheter-based device coupled with a pulse generator for use to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, wherein the plasmids or genes are incorporated within a polymer matrix such as any known synthetic polymer, *e.g.,* polyglycoglides, entire disclosure, abstract, column 3, lines 31-67, column 4 through column 5, column 13, last full paragraph, and entire column 15.

Absent evidence to the contrary, Brown anticipates, or the alternative, render the claimed invention as a whole *prima facie* obvious.

Claims 1-5, 8, 9, 10, 25-28, 32, 33, 35, 49-52 are rejected under 35 USC 103(a), as being unpatentable over Brown, III *et al.* (US 6,219,577 B1, referred as Brown) taken with Gunzburg (WO 96/28563).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide encodes an antimicrobial peptide, Brown is applied has indicated above. Brown does not teach that the polynucleotide encodes a microbial peptide, however at the time the invention was made, Gunzburg teaches genes encoding antimicrobial peptides can be used in gene therapy for the treatment of mammalian tumours, viral infections, entire disclosure, especially pages 6-7.

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device to enhance the delivery of an antimicrobial gene in the treatment of tumour or viral infections. One of ordinary skill in the art would have been motivated to employ the catheter based medical device in the treatment of using antimicrobial peptide encoding genes in treating tumours and/or viral infection because Brown teaches a medical device composed of a catheter-based device coupled with a pulse generator for use to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because Gunzburg teaches genes encoding antimicrobial peptides can be used in gene therapy for the treatment of mammalian tumours, viral infections.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1, 4-6, 25, 28-30 are rejected under 35 USC 103(a) as being unpatentable over Brown taken with either Naghavi (US Pat No. 6,451,044 B1) or Soykan (US Pat No. 6,206,914 B1).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide is entrapped within a natural porous polymer such as collagen, Brown is applied has indicated above. Brown does not teach that the polymer applicable for use to enhance the delivery of genes and/or plasmids is a natural porous polymer such as collagen, both Naghavi and Soykan teach that medical devices comprising a natural porous polymer such as collagen is well suitable for use in enhancing the delivery of therapeutic DNA to a target cell (entire disclosure, particularly column 22 and column 10, last full par., respectively).

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device comprising a natural porous polymer such as collagen to enhance the delivery of any therapeutic DNA to a target cell. One of ordinary skill in the art would have been motivated to employ the catheter based medical device composed of a natural porous polymer such as collagen in the delivery of any therapeutic DNA to a target cell because Brown teaches that a medical device composed of a catheter-based device comprising any polymeric matrix known in the prior art can be used to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because Naghavi

and Soykan teach that medical devices comprising a natural porous polymer such as collagen is well suitable for use in enhancing the delivery of therapeutic DNA to a target cell (entire disclosure).

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 1-5, 8, 9, 10-14, 25-28, 32, 33, 35-38, 49-52 are rejected under 35 USC 103(a) as being unpatentable over Brown taken with German (US 2003/0078266 A1).

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide encodes an antimicrobial peptide, Brown is applied has indicated above. Brown does not teach that the polynucleotide encodes a microbial peptide, however, German teaches genes encoding antimicrobial peptides can be used in gene therapy for the treatment of microbioal infection, page 6, par.0083 and 0085.

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device to enhance the delivery of an antimicrobial gene in the treatment of any microbioal infections. One of ordinary skill in the art would have been motivated to employ the catheter based medical device in the treatment of using antimicrobial peptide encoding antimicrobial polypeptides in treating a microbial or viral infection because Brown teaches a medical device composed of a catheter-based device coupled with a pulse generator for use to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because German teaches that gene therapy of using non-viral vectors encoding a secretory antimicrobial peptides is effective for the treatment of any microbial or viral infection.

To the extent that the claims are readable to the claimed medical device, wherein the polynucleotide is condensed, linked to a targeting ligand, or complexed to a liposomal carrier, Brown is applied has indicated above. Brown does not teach that the polynucleotide is condensed, linked to a targeting ligand, or complexed to a liposomal carrier. However at the time the invention was made, German teaches that lipsomal carrier comprising a therapeutic DNA, and that therapeutic DNA conjugated to polylysine and a targeting ligand are routinely used in the prior art to preserve and enhance the delivery of the DNA to a target cell (page 7, pars. 0095 and 0096).

It would have been obvious for one of ordinary skill in the art to employ the catheter based medical device of Brwon to deliver a liposomal carrier or a condensed DNA/polylysine/targeting complex to enhance the delivery and expression any therapeutic DNA including those encoding an antimicrobial polypeptide to a target cell. One of ordinary skill in the art would have been motivated to employ the catheter based medical device of Brown in the delivery of any therapeutic DNA complex such as those described in German to a target cell because Brown teaches that a medical device composed of a catheter-based device comprising any carrier known in the prior art can be used to enhance the delivery of any pharmaceutical known in the prior art such as plasmids, genes to a target cell, and because German not only teaches that liposomal carriers complexed to any desired therapeutic DNA including those encoding a microbial peptide can be used to enhance and preserve the delivery and expression of the DNA, but also teaches that a condensed DNA/polylysine/targeting complex is well suitable for use in enhancing the delivery of any therapeutic DNA to a target cell.

Thus, the claimed invention as a whole was *prima facie* obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER